DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service JEH
912721
Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

May 11, 2001

VIA FEDERAL EXPRESS

FACILITY ID# 223504

Edward H. Lazar, M.D., President
OB GYN Physicians Group of Memphis
6570 Stage Road, Suite 160
Memphis, TN 38134

Warning Letter No. 01-NSV-25

Dear Dr. Lazar:

Your facility was inspected on April 27, 2001 by a representative of the State of Tennessee on contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 1

The system to communicate results is not adequate for site OB GYN Physicians Group of Memphis because:

- **There is no system in place to provide timely lay summaries**

This specific deficiency appeared on the Post Inspection Report, which was given to your facility at the close of your inspection, along with instructions on how to respond to this finding. This deficiency may be symptomatic of serious problems that could compromise the quality of mammography at your facility and potentially overexpose both patients and employees involved with mammography.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of this deficiency as identified and to promptly initiate permanent corrective action.

If you fail to properly address this deficiency, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.

- suspend or revoke a facility's FDA certificate for failure to comply with the Standards

- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of any similar violations.

If your facility is unable to complete this corrective action within 15 working days, you should state the reason for the delay and the time within which the correction will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125, with a copy to the State of Tennessee. Should you have questions regarding this letter or MQSA standards, you may call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,

Carl E. Draper

Carl E. Draper
Director, New Orleans District

CED:KRS:man

Cc: Darlene Nalepa-Whitmill
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